

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA *et al.*
ex rel. JULIE LONG,

Plaintiffs,

v.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No. 16-CV-12182-FDS

**NOTICE OF RULE 30(b)(6) DEPOSITION OF
DEFENDANT JANSSEN BIOTECH, INC.**

TO: Ethan M. Posner
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PLEASE TAKE NOTICE that, pursuant to Rules 26 and 30 of the Federal Rules of Civil Procedure and the parties' Remote Deposition Protocol, plaintiff-relator Julie Long, by and through her counsel, will take the deposition by oral examination of defendant Janssen Biotech, Inc. The deposition will be taken remotely by videoconference before a person duly authorized to administer oaths in accordance with Federal Rule of Civil Procedure 28. The deposition will be recorded by stenographic means and videotaped by Hudson Court Reporting. The deposition will begin at 9:30 a.m. ET on _____, 2024, or on another date agreed to by counsel. If the deposition is not completed on that day, it will continue day to day until completed.

PLEASE TAKE FURTHER NOTICE that, in accordance with Federal Rule of Civil Procedure 30(b)(6), Janssen Biotech, Inc., shall designate as its representative(s) one or more persons who consent to testify on its behalf, knowledgeable about the subject matters listed (each a “Topic for Examination” and together the “Topics”) on the attached “Schedule A.” This Rule 30(b)(6) Notice supersedes the prior notice dated March 8, 2023.

Dated: May 6, 2024

/s/ Casey M. Preston

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SCHEDULE A

Definitions

1. The masculine, feminine, or neutral pronoun shall not exclude other genders.
2. The singular includes the plural and vice versa.
3. The present tense shall be construed to include the past tense and vice versa.
4. The word “including” shall be read to mean “including without limitation.”
5. “ABS” means individuals who held the Area Business Specialist or equivalent position.
6. “AKS” means the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.
7. “All,” “any,” and “each” shall each be construed as encompassing any and all.
8. “And” and “or” mean “and/or” and be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.
9. “Concerning” means relating to, referring to, in connection with, in respect of, describing, discussing, evidencing, reflecting, showing, setting forth, containing, or constituting.
10. “FCA” means the False Claims Act, 31 U.S.C. § 3729 *et seq.*
11. “Federal Government” means any agency or sub-agency of the United States, including, but not limited to, the Department of Health and Human Services, the Office of the Inspector General for the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, and the Department of Justice, as well as all representatives, agents, employees, and contractors thereof.
12. “IOI” means an in-office infusion suite or infusion business operated by a physician practice.
13. “IOI Customers” the rheumatology and gastroenterology physician practices including the Phase 1 Accounts (including all owners, shareholders, partners, limited partners, and persons employed by the physician practices) to which You provided the IOI Support and Programs through which the IOI Support was provided.
14. “IOI Support” refers to the collection or package of Services and related Programs through which You provided Services (through ABSs and/or Outside Consultants) to IOI Customers including the Phase 1 Accounts.

15. “Outside Consultants” means any person not employed by You that You paid to provide and/or develop certain Services and/or Programs such as Xcenda and Akin Gump.

16. “Person” means any natural person or any business, legal, or governmental entity or association.

17. “Phase 1 Accounts” refers collectively to the following physician practices and all owners, shareholders, partners, limited partners, persons employed by the physician practices, as well as all subsidiaries, affiliates, predecessors, and successors:

- (1) Altoona Arthritis & Osteoporosis Center
- (2) Arthritis & Osteoporosis Center
- (3) Berks Center for Digestive Health (a/k/a Berks Center for Digestive Disease; Digestive Disease Associates; Digestive Disease of West Reading (DDWR))
- (4) Capital Arthritis and Rheumatology Associates (f/k/a George Kunkel, M.D.)
- (5) Cumberland Valley Rheumatology (f/k/a Schlansky & Clawson)
- (6) Ellen M. Field-Rubbo, M.D.
- (7) Emkey Arthritis & Osteoporosis Clinic
- (8) Jackson Siegelbaum Gastroenterology (f/k/a West Shore Endoscopy Center)
- (9) Pottstown Medical Specialists (a/k/a PMSI)
- (10) Sanford, Roumm, and Acharya Rheumatology (f/k/a Sanford and Roumm Rheumatology)
- (11) U.S. Digestive Health (f/k/a Lancaster Gastroenterology (LGI))
- (12) U.S. Digestive Health (f/k/a Regional Gastroenterology Associates of Lancaster (RGAL))

18. “Plaintiff” means plaintiff relator Julie Long.

19. “Programs” means the consultative or educational meetings or sessions (or their substantive equivalents) that You presented or conducted (through ABSs and/or Outside Consultants), under national directives, to IOI Customers including the Phase 1 Accounts (whether provided in person, telephonically, by webinar, or other means):

- (1) Becoming an Alternative Site of Care for Therapy with Remicade in Your Community

- (2) Billing and Coding for Infusions
- (3) Checkpoints for Infusion Center Optimization
- (4) Considerations for Proactive Practice Management (a/k/a Current Considerations for Proactive Practice Management; Proactive Practice Management)
- (5) Considerations for Standard Operating Procedures in the Infusion Suite
- (6) Considerations for Working with a Specialty Pharmacy (a/k/a Specialty Pharmacy Considerations)
- (7) Electronic Health Records and Meaningful Use (Part 1 and/or Part 2)
- (8) Emerging Trends in Health Care
- (9) Enhancing Patient Care and Access
- (10) Exceptions and Appeals
- (11) Hot Buttons
- (12) ICD-10
- (13) In-Office Infusion Drug Procurement Models
- (14) Infusion Optimization Modeler (a/k/a IOM)
- (15) Infusion Referrals: Improving the Continuity of Care (a/k/a Coordinating the Continuity of Care with Infusion Referrals; Quality Improvements in Coordinating the Continuity of Care with Infusion Referrals)
- (16) Infusion Services Review (a/k/a iBiz; Infusion Business Review)
- (17) Infusion Suite Scheduling and Staffing
- (18) Infusion Therapy Services Provided in Converted ASC Space (a/k/a Infusion Services and Ambulatory Surgical Centers (ASCs) - Planning Considerations; ASC Space Reclassification for Infusion Therapy)
- (19) Inventory and Supply Management
- (20) IV Therapy: An Important Option for Your Patients (a/k/a Why IV)
- (21) Managing Biologics in the Physician Office (a/k/a MBPO)

- (22) Medicare Audits
- (23) Medicare Quality Payment Program: A Focus on MIPS
- (24) Patient Experience in the Infusion Suite
- (25) Payer Relationship Management
- (26) Practice Compliance for Remicade
- (27) Private Payer Contracting Considerations (Part 1 and/or Part 2) (a/k/a Private Payer Contracting Considerations for Therapy with Remicade)
- (28) Quality of Care in the Infusion Suite
- (29) Raising the Infusion Suite Experience (a/k/a RISE)
- (30) Remicade Account Review (a/k/a Physician Office Account Review for Remicade)
- (31) Setting Up In-Office Infusions of Remicade
- (32) Specialty Drug Market Dynamics
- (33) Successful Implementation of a New Infusion Suite
- (34) Successful Implementation of a New Infusion Suite for Gastroenterology Practices
- (35) Successful Infusion Site Management for Gastroenterology (a/k/a Successful Infusion Suite Management for Gastroenterology)
- (36) Akin Gump teleconferences, including, but not limited to: Medicare Physician Payment Update; Healthcare Reform Update; and Medicare Shared Savings Program and Accountable Care Organization Proposed Rule Update

20. “Services” means the advisory, educational, and consultative assistance, support, and services concerning the topics listed below that You provided (through ABSs and/or Outside Consultants), under national directives, to IOI Customers including the Phase 1 Accounts:

- (1) establishing and opening an initial IOI
- (2) opening an IOI at another location
- (3) the practice’s readiness for administering infusions in a new IOI
- (4) the optimal design, furniture, and décor of the IOI

- (5) using a gastroenterology practice's ambulatory surgical center as an IOI (reclassifying ASC space to office space to allow for provision of infusion services in compliance with Medicare requirements)
- (6) identifying and addressing a practice's IOI's operational needs and challenges
- (7) enhancements to the IOI that would increase patient satisfaction (to attract more patients and enable the practices to negotiate higher reimbursement rates from private payers and patients)
- (8) the infusion business model
- (9) growing or maintaining the IOI
- (10) the assessment and evaluation of the IOI's infusion procedure volume and capacity
- (11) adding other infusion service lines or treatments to an IOI
- (12) making other physicians, who do not perform infusions in their offices, aware of the practice's IOI and seeking referral arrangements with such physicians
- (13) operating IOIs more efficiently and profitably (and lowering overhead costs)
- (14) optimizing the infusion schedule (maximizing infusion procedures and minimizing staffing time and costs)
- (15) establishing and implementing standard operating procedures to improve the IOI workflow and billing processes
- (16) management of the inventory of infusible drugs and infusion procedure supplies
- (17) acquisition of drugs administered in the IOI
- (18) management of the financial risks related to infusing drugs in the IOI
- (19) tracking accounts receivable and payments from payers and patients for infusion drugs and services
- (20) obtaining coverage exceptions and overturning payment denials through appeals
- (21) private payer coverage and reimbursement trends
- (22) best contracting practices and management of relationships with private payers and the government health care programs

- (23) negotiating higher reimbursement rates from private payers for frequently billed services and drugs (starting with benchmarking and evaluating existing terms of contracts with private payers and reimbursement rates)
- (24) government legislative and policy changes, programs, and trends that impact physician practices
- (25) avoiding and responding to an audit of the practice's claims for payment by Medicare
- (26) qualifying for incentive payments and avoiding penalties under the Health Information Technology for Economic and Clinical Health (HITECH) Act and Medicare's Electronic Health Record Incentive Program (including achieving meaningful use criteria with electronic health records)
- (27) qualifying for incentive payments under Medicare's Electronic-Prescribing (eRx) Incentive Program
- (28) qualifying for the incentive payments and payment adjustments under CMS's Physician Quality Reporting System (PQRS)
- (29) qualifying for the incentive payments under Medicare's Merit-Based Incentive Payment System
- (30) preparing the practice for conversion to the ICD-10 coding system

21. "You" and "Your" mean defendant Janssen Biotech, Inc., and all its parents, U.S. and non-U.S. subsidiaries, divisions, affiliates, predecessors, successors, officers, directors, employees, agents, partners, limited partners, and independent contractors, as well as aliases, trade names, or business names used by, or formerly used by, any of the foregoing, including, but not limited to, Centocor Ortho Biotech Inc., Centocor, Inc., Ortho-McNeil Janssen Scientific Affairs, LLC, Ortho-McNeil-Janssen Pharmaceuticals, Inc., Johnson & Johnson, Johnson & Johnson Pharmaceutical Services, LLC, Johnson & Johnson Services, Inc., Janssen Scientific Affairs, LLC, and Janssen Pharmaceuticals, Inc.

Topics for Examination

- 1. For each Program (or its substantive equivalent), the following information:
 - (a) When You started providing the Program to IOI Customers.
 - (b) When You stopped providing the Program to IOI Customers.
 - (c) Whether the Program was branded or unbranded.

- (d) Whether You provided the Program to all physician practices that prescribed Remicade and/or Simponi ARIA or only to targeted physician practices.
- (e) The factors that were considered in determining which physician practices received the Program.
- (f) Whether You paid a vendor or Outside Consultant to develop the Program and the approximate amount You paid the vendor or Outside Consultant to develop the Program.
- (g) Whether the Program was provided to IOI Customers in person and/or remotely by an ABS.
- (h) Whether You paid an Outside Consultant to provide the Program to IOI Customers in person and/or remotely and the amount You paid for the presentation of the Program.
- (i) Whether You had ABSs in the Oncology division provide the Program (or substantive equivalent) to oncology practices.
- (j) All Your purposes and objectives in providing the Program to IOI Customers.
- (k) The amount You charged IOI Customers for the Program.
- (l) The actions You took to evaluate the benefit or value, including the independent value, that IOI Customers received from the Program.
- (m) Your belief and knowledge concerning the benefit and/or value, including the independent value, that IOI Customers received from the IOI Support, the bases for such belief. Included in this topic are the results of any assessments or analyses You performed to review or determine the benefit or value, including the independent value, that IOI Customers received from the IOI Support.
- (n) Your knowledge concerning the prescriptions and infusions of Remicade and/or Simponi ARIA to patients including Medicare patients that resulted from and/or were influenced by Your provision of the Program to IOI Customers. Included in this topic are the results of any assessments or analyses You performed concerning whether receiving the Program caused, impacted, or influenced the recipient to prescribe and/or utilize Remicade and/or Simponi ARIA.
- (o) Whether you advertised to physicians and patients that you provided the Program to IOI Customers.
- (p) All actions You took to determine whether providing the Program to IOI Customers violated the AKS and/or FCA.
- (q) Whether the Program was reviewed by Your legal department separate and apart from any review conducted by an attorney in connection with a Promotional

Review Committee (or equivalent committee) review. Included in this topic are the review process, the approximate dates of the reviews, and persons from the legal department who performed the reviews.

- (r) Your belief and knowledge concerning whether providing the Program to IOI Customers violated the AKS and the bases for such belief.

Relevant time period: Except for 1(b), from the creation of the Program to until February 19, 2016. For 1(b), from the creation of the Program to until the present.

- 2. For the IOI Support as a whole, the following information:
 - (a) Whether You provided the IOI Support to all physician practices that prescribed Remicade and/or Simponi ARIA or only to targeted physician practices.
 - (b) The factors that were considered in determining which physician practices received the IOI Support.
 - (c) All Your purposes and objectives in providing the IOI Support to IOI Customers.
 - (d) The amounts You spent each year providing the IOI Support to IOI Customers (through ABSs and Outside Consultants) and Your return on investment concerning the provision of the IOI Support to IOI Customers.
 - (e) The amount You charged IOI Customers for the IOI Support.
 - (f) The actions You took to evaluate the benefit or value, including the independent value, that IOI Customers received from the IOI Support.
 - (g) Your belief and knowledge concerning the benefit and/or value, including the independent value, that IOI Customers received from the IOI Support, the bases for such belief. Included in this topic are the results of any assessments or analyses You performed to review or determine the benefit or value, including the independent value, that IOI Customers received from the IOI Support.
 - (h) Your knowledge concerning the prescriptions and infusions of Remicade and/or Simponi ARIA to patients including Medicare patients that resulted from and/or were influenced by Your provision of the IOI Support to IOI Customers. Included in this topic are the results of any assessments or analyses You performed concerning whether receiving the IOI Support caused, impacted, or influenced the recipient to prescribe and/or utilize Remicade and/or Simponi ARIA.
 - (i) Whether You advertised to physicians and patients that you provided the IOI Support to IOI Customers.
 - (j) All actions You took to determine whether providing the IOI Support and Programs to IOI Customers violated the AKS and/or FCA.

- (k) Whether the provision of the IOI Support to IOI Customers was reviewed by Your legal department separate and apart from any review conducted by an attorney in connection with a Promotional Review Committee (or equivalent committee) review. Included in this topic are the review process, the approximate dates of the reviews, and persons from the legal department who performed the reviews.
- (l) Your belief and knowledge concerning whether providing the IOI Support to IOI Customers violated the AKS and the bases for such belief.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.

3. Your methods and practices for tracking and/or recording the following information concerning the Programs provided to IOI Customers:

- (a) When an ABS or Outside Consultant provided advice, education, or assistance to a health care provider or his/her staff concerning opening an IOI within a physician practice.
- (b) When an ABS or Outside Consultant provided a Program to an IOI Customer.
- (c) The persons from IOI Customers who attended a Program.
- (d) The benefit and/or value, including the independent value, of a Program to the recipient.
- (e) The amount You spent providing the Program and/or IOI Support (through ABSs and Outside Consultants).
- (f) The return You received from providing the Program and/or IOI Support.

Relevant time period: From when You began providing the IOI Support and Programs to IOI Customers to until February 19, 2016.

4. Your knowledge and understanding concerning (a) the AKS, (b) the safe harbor regulations, and (c) the Office of Inspector General for the U.S. Department of Health and Human Services's guidance concerning the provision of product-related services to customers.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.

5. The actions You took to train Your employees who were responsible for evaluating the legality of providing the IOI Support concerning conduct prohibited by the AKS, including the provision of services that have independent value to customers.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.

6. Whether any of Your employees or agents advised or expressed a concern or belief that Your provision of the IOI Support and/or Programs to IOI Customers violated: (a) the law including the AKS and/or FCA, and/or (b) Your compliance policies concerning the provision of consulting, product-related services, and/or educational services to customers.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.

7. All legal actions that You have settled and/or a judgment or verdict was entered against You in which it was alleged that You violated the AKS.

8. Your asserted belief that You acted in good faith when providing the IOI Support to IOI Customers and the asserted bases for this belief.

9. The Federal Government's investigation(s) referenced in Your answer to Interrogatory 15 and any findings and/or determinations that the Federal Government communicated to You in connection with the Federal Government's investigation(s).

10. Your reasons for not reporting the IOI Support and/or Programs that were provided to IOI Customers to the Centers for Medicare & Medicaid Services under 42 C.F.R. § 403.904 and 42 U.S.C. § 1320a-7h, including identification of the individuals who made the decision(s) to not report the IOI Support and/or Programs that were provided to IOI Customers to Centers for Medicare & Medicaid Services.

Relevant time period: From Your first report to the Centers for Medicare & Medicaid Services under 42 C.F.R. § 403.904 and 42 U.S.C. § 1320a-7h to until February 19, 2016.

11. Your compliance policy and/or guidance document (and equivalents thereof) concerning the topics of (i) providing consulting and/or services to customers (*see, e.g.*, JANSSENBIO-037-00000844 (Guidance Doc. 2); JANSSENBIO-018-00000067; JANSSENBIO-031-00016550; JANSSENBIO-045-00000537 (Ch. 14)), (ii) providing reimbursement information and services to customers (*see, e.g.*, JANSSENBIO-008-00000777 (Guidance Doc. 25); JANSSENBIO-031-00016546; JANSSENBIO-018-00001010; JANSSENBIO-064-00003344; JANSSENBIO-045-00000537 (Ch. 13)), and/or (iii) providing educational support and/or programs to customers (*see, e.g.*, JANSSENBIO-037-00001252; JANSSENBIO-055-00004234; JANSSENBIO-031-00016492) that was in effect at any time during the period 2001 to February 2020.

12. The reasons why You revised or replaced the compliance policy and/or guidance document concerning the provision of consulting and product-related services in 2015. *See, e.g.*, JANSSENBIO-064-00003167.

13. The development, review, approval, monitoring, evolution, and history of the strategy to provide the IOI Support and Programs to IOI Customers.

Relevant time period: From the creation of the strategy to provide the IOI Support and Programs to IOI Customers to until February 19, 2016.

14. The infusion business model, IOI business model, and/or Remicade business model that You promoted to IOI Customers.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.

15. Why You transferred responsibility for the Site of Care field team including ABSs from Immunology Sales to Immunology Marketing in 2015.

16. Your compensation system for ABSs including sales bonuses and contests and the Management By Objective (MBO) system and bonuses.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.

17. The corporate organization and responsibilities of the departments, groups, and teams (such as sales, marketing, legal, compliance, regulatory, analytics, sales training, and finance) who had significant involvement in the strategy to provide the IOI Support to IOI Customers.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.